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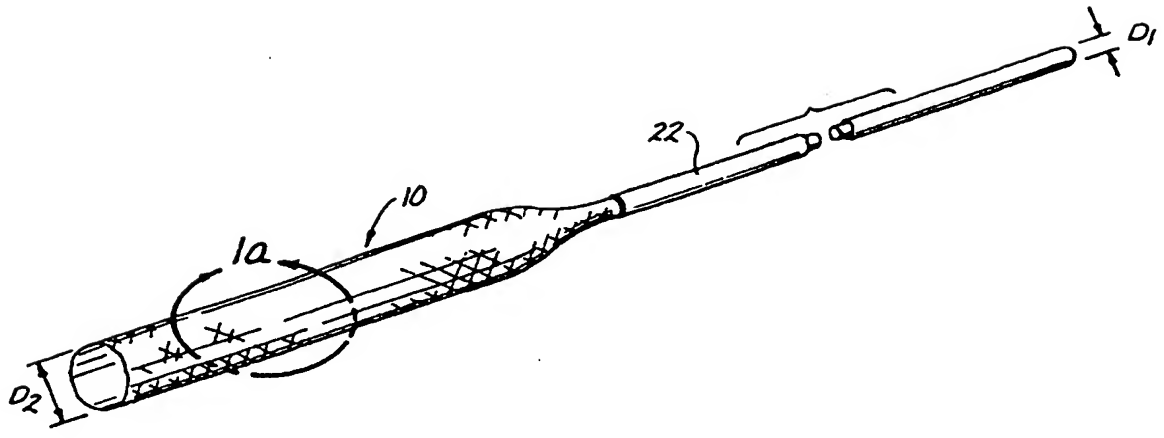

(57) Abstract

Stented tubular grafts of expanded, sintered polytetrafluoroethylene (PTFE). The stented PTFE grafts of the present invention include an integrally stented embodiment, an externally stented embodiment, and an internally stented embodiment. In each embodiment, the stent may be either self-expanding or pressure-expandable. Also, in each embodiment, the stent may be coated or covered with a plastic material capable of being affixed (e.g., heat fused) to PTFE. Manufacturing methods are also disclosed by the individual components of the stented grafts, are preassembled on a mandrel and are subsequently heated to facilitate attachment of the PTFE layer(s) to one another and/or to the stent. Optionally, the stented graft may be post-flexed and post-expanded following its removal from the mandrel to ensure that the stented graft will be freely radially expandable and/or radially contractible over its full intended range of diameters.

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STENTED, RADIALLY EXPANDABLE, TUBULAR PTFE GRAFTS

Field of the Invention

The present invention pertains generally to medical devices and their methods of manufacture, and more particularly to tubular, polytetrafluoroethylene (PTFE) grafts having integral, radially expandable stents, for implantation in a cavities or passageways (e.g., ducts or blood vessels) of the body.

Background of the Invention

A. Stents

The prior art has included a number of radially expandable stents which may be initially deployed in a radially collapsed state suitable for transluminal insertion via a delivery catheter, and subsequently transitioned to a radially expanded state whereby the stent will contact and engage the surrounding wall or the anatomical duct or body cavity within which the stent has been positioned. Such stents have been used to support and maintain the patency of blood vessel lumens (e.g., as an adjuvant to balloon angioplasty) and to structurally support and/or anchor other apparatus, such as a tubular endovascular grafts, at desired locations within a body cavity or passageway (e.g., to anchor a tubular endovascular graft within a blood vessel such that the graft forms an internal conduit through an aneurysm or site of traumatic injury to the blood vessel wall).

Many stents of the prior art have been formed of individual member(s) such as wire, plastic, metal strips, or mesh which have been bent, woven, interlaced or otherwise fabricated into a generally cylindrical configuration. These stents of the prior art have generally been classified into two major categories --a) "self-expanding" stents, and b) "pressure expandable" stents.

i) Self-expanding Stents

Self-expanding stents are typically formed of spring metal, shape memory alloy, or other material which is resiliently biased toward it's fully radially expanded configuration or otherwise capable of self-expanding to it's fully radially expanded configuration without the need for the exertion of outwardly directed radial force upon the stent by some extraneous expansion apparatus (e.g., a balloon or mechanical expander tool). These self-expanding stents may be initially radially compressed and loaded into a small diameter delivery catheter or alternatively mounted upon the outer surface of a delivery catheter equipped with some means for restraining or maintaining the stent in it's radially compressed state. Thereafter, the delivery catheter is inserted into the body and is advanced to a position where the stent is located at or near the site at which it is to be implanted. Thereafter, the stent is expelled out of (or released from) the delivery catheter and allowed to self-expand to it's full radial diameter. Such expansion of the stent causes the stent to frictionally engage the surrounding wall of the body cavity or passageway within which the stent has been positioned. The delivery catheter is then extracted, leaving the self-expanded stent at it's intended site of implantation. Some examples of self-expanding stents of the prior art include those described in United States Patent Nos. 4, 655, 771 (Wallsten et al.); 4,954,126 (Wallsten): 5, 061, 275 (Wallsten et al.); 4,580,568 (Gianturco); 4,830,003 (Wolf et al.); 5,035,706 (Gianturco et al.) and 5,330,400 (Song).

ii) Pressure-Expandable Stents

The pressure-expandable stents of the prior art are typically formed of metal wire, metal strips, or other malleable or plastically deformable material, fabricated into a generally cylindrical configuration. The pressure-expandable stent is initially disposed in a

collapsed configuration having a diameter which is smaller than the desired final diameter of the stent, when implanted in the blood vessel. The collapsed stent is then loaded into or mounted upon a small diameter delivery catheter. The delivery catheter is then advanced to its desired location within the vasculature, and a balloon or other stent-expansion apparatus (which may be formed integrally of or incorporated into the delivery catheter) is utilized to exert outward radial force on the stent, thereby radially expanding and plastically deforming the stent to it's intended operative diameter whereby the stent frictionally engages the surrounding blood vessel wall. The material of the stent undergoes plastic deformation during the pressure-expansion process. Such plastic deformation of the stent material causes the stent to remain in its radially expanded operative configuration. The balloon or other expansion apparatus is then deflated/collapsed and is withdrawn from the body separately from, or as part of, the delivery catheter, leaving the pressure-expanded stent at it's intended site of implantation.

Some examples of pressure-expandable stents of the prior art include those described in United States Patent Nos. 5,135,536 (Hillstead); 5,161,547 (Tower); 5,292,331 (Boneau); 5,304,200 (Spaulding) and 4,733,665 (Palmaz).

B. PTFE Vascular Grafts:

Fluoropolymers, such as polytetrafluoroethylene, have been heretofore used for the manufacture of various types of prosthetic vascular grafts. These vascular grafts are typically of tubular configuration so as to be useable to replace an excised segment of blood vessel.

The tubular PTFE vascular grafts of the prior art have traditionally been implanted, by open surgical techniques, whereby a diseased or damaged segment of blood vessel is surgically excised and removed, and the tubular bioprosthetic graft is then anastomosed into the host blood vessel as a replacement for the previously

removed segment thereof. Alternatively, such tubular prosthetic vascular grafts have also been used as bypass grafts wherein opposite ends of the graft are sutured to a host blood vessel so as to form a bypass conduit around a diseased, injured or occluded segment of the host vessel.

In general, many tubular prosthetic vascular grafts of the prior art have been formed of extruded, porous PTFE tubes. In some of the tubular grafts of the prior art a PTFE tape is wrapped about and laminated to the outer surface of a tubular base graft to provide reinforcement and additional burst strength. Also, some of the prior tubular prosthetic vascular grafts have included external support member(s), such as a PTFE beading, bonded or laminated to the outer surface of the tubular graft to prevent the graft from becoming compressed or kinked during implantation. These externally supported tubular vascular grafts have proven to be particularly useful for replacing segments of blood vessel which pass through, or over, joints or other regions of the body which undergo frequent articulation or movement.

One commercially available, externally-supported, tubular vascular graft is formed of a PTFE tube having a PTFE filament helically wrapped around, and bonded to, the outer surface of the PTFE tube. (IMPRA Flex™ Graft, IMPRA, Inc., Tempe, Az)

One other commercially available, externally-supported, tubular vascular graft comprises a regular walled, PTFE tube which has PTFE reinforcement tape helically wrapped around, and bonded to, the outer surface of the PTFE tube and individual rings of Fluorinated Ethylene Propylene (FEP) rings disposed around, and bonded to, the outer surface of the reinforcement tape. (FEP ringed ePTFE vascular graft, W.L. Gore & Associates, Inc., Flagstaff, AZ)

C. Stented Grafts:

The prior art has also included a number of "stented grafts". These stented grafts typically comprise a-self-expanding or pressure-expandable stent which is affixed to or formed within a pliable tubular graft. Because of their radial compressibility/expandability, these stented grafts are particularly useable in applications wherein it is desired to insert the graft into an anatomical passageway (e.g., blood vessel) while the graft is in a radially compact state, and to subsequently expand and anchor the graft to the surrounding wall of the anatomical passageway. More recently, methods have been developed for introducing and implanting tubular prosthetic vascular grafts within the lumen of a blood vessel, by percutaneous or minimal incision means. Such endovascular implantation initially involves translumenal delivery of the graft, in a compacted state, by way of a catheter or other transluminally advancable delivery apparatus. Thereafter, the graft is radially expanded and anchored to the surrounding blood vessel wall, thereby holding the graft at its intended site of implantation within the host blood vessel. An affixation apparatus such as a stent, is typically utilized to anchor at least the opposite ends of the tubular graft to the surrounding blood vessel wall. One particular application for endovascular grafts of this type is in the treatment of vascular aneurysms without requiring open surgical access and resection of the aneurysmic blood vessel. Also, such stented grafts may also be useable to treat occlusive vascular disease--especially in cases where the stented graft is constructed in such a manner that the tubular graft material forms a complete barrier between the stent and the blood which is flowing through the blood vessel. In this manner the tubular graft material may serve as a smooth, biologically compatible, inner "covering" for the stent, thereby preventing a) turbulent blood-flow as the blood flows

over the wire members or other structural material of which the stent is formed, b) immunologic reaction to the metal or other material of which the stent is formed, and c) a barrier to separate a diseased or damaged segment of blood vessel from the blood-flow passing therethrough. Such prevention of turbulent blood-flow and/or immunologic reaction to the stent material is believed to be desirable as both of these phenomena are believed to be associated with thrombus formation and/or restenosis of the blood vessel.

Other uses for stented grafts may include restoring patency to, or re-canalizing, other anatomical passageways such as ducts of the biliary tract, digestive tract and/or genito-urinary tract.

Many of the stented grafts known in the prior art have utilized woven or knitted material, such as polyester fiber, as the graft material.

There exists a need for the development of a radially expandable, stented graft formed of a continuous, tubular ePTFE tube because the inherent properties of PTFE may offer various clinical advantages over the woven polyester and other graft materials which have been previously used in stented grafts of the prior art.

Summary of the Invention

The present invention is directed to stented, tubular, PTFE grafts and their methods of manufacture. In general, the present invention may exist in any of three (3) separate embodiments, depending upon whether the stent component of the graft is formed integrally (i.e., within) the tubular PTFE graft, externally (i.e., on the outer surface of) the tubular PTFE graft, or internally (i.e., on the inner lumenal surface) of the PTFE tubular graft. Each of these three separate embodiments of the invention may be self expanding (i.e., incorporating a self-expanding stent) or pressure-

expandable (i.e., incorporating a pressure-expandable stent.

In accordance with a first embodiment of the invention, there is provided an integrally stented PTFE graft which comprises a tubular PTFE base graft preferably of a density less than 1.6 g/cc, a radially expandable stent surrounding the outer surface of the tubular base graft, and an outer PTFE layer having a density of less than 1.6 g/cc. The tubular outer layer is fused to the tubular base graft through lateral openings or perforations formed in the stent. A polymer coating, such as a PTFE coating, may be disposed on the stent to further facilitate fusing or boding of the stent to the base tube and/or outer tubular layer.

In accordance with a second embodiment of the invention, there is provided an externally stented, tubular PTFE graft which comprises a radially compressible/expandable stent having a ePTFE tube of less than 1.6 g/cc density coaxially disposed within the stent, with the outer surface of the tubular ePTFE graft being fused or attached to the stent. A polymer coating, such as PTFE or any other plastic which may be fused or adhered to PTFE, may be applied to or formed on the stent to facilitate the desired fusion or attachment of the tube graft to the stent, and/or to improve the biocompatibility of the stent.

In accordance with a third embodiment of the invention, there is provided an internally stented, tubular PTFE graft comprising a tubular outer layer formed of ePTFE having a density of less than 1.6 g/cc, and a radially expandable stent. The stent is coaxially disposed within the lumen of the tubular outer layer, and fused or attached thereto. The stent may be covered with a polymer coating, such as PTFE or other biocompatable plastic capable of adhering or fusing to PTFE, to facilitate the desired fusion or attachment of the stent to the outer tubular layer, and/or to improve the

biocompatability of the stent. Additionally or alternatively, PTFE particles may be disposed between the tubular outer layer and the tubular base graft to facilitate adhering or fusing of these two layers to one another, and/or to the stent. Such PTFE particles may be disposed between the inner base graft and outer tubular layer by applying or depositing PTFE liquid dispersion therebetween, or by depositing dry PTFE resin powder therebetween.

Any of above-summarized three (3) separate embodiments of the invention may be manufactured by a method which comprises the steps of: a) initially positioning a generally cylindrical stent of either the self-expanding or pressure-expandable variety in contacting coaxial relation with the tubular ePTFE base graft and/or the tubular ePTFE outer layer, upon a cylindrical mandrel or other suitable support surface, and b) subsequently fusing the fuse (i.e., heating to a lamination temperature) assembled components (i.e., the stent in combination with the inner base graft and/or outer tubular layer) of the stented graft into a unitary stented graft structure. In integrally stented embodiments where both the tubular ePTFE base graft and the tubular ePTFE outer layer are present, such heating will additionally cause the tubular outer layer to fuse to the inner tubular base graft, through lateral openings or perforations which exist in the stent. The stent may be surface treated, abraded, or coated with a plastic capable of adhering or fusing to ePTFE to facilitate attachment of the stent to the adjacent outer layer and/or inner base graft upon subsequent heating, application of solvent or other suitable adhesion promoting technique. In instances where a plastic coating is formed on the stent, such coating may be in the nature of a tube or film which is applied to the stent prior to assembly and mounting of the stented graft components on the mandrel or other support surface.

Also, in embodiments where both the outer tubular layer and tubular base graft are used, aqueous PTFE dispersion, powdered PTFE resin or other flowable plastic material, may be deposited between the outer tubular layer and inner tubular base graft at the time of assembly (prior to heating) to further facilitate fusion of the outer tubular layer and/or inner tubular base graft to the stent and/or to one another.

By the above-described materials and methods of construction, the stented PTFE grafts of the present invention are capable of radially expanding and contracting without excessive puckering, wrinkling or invagination of the PTFE graft material. Furthermore, in embodiments wherein the stent is constructed of individual members which move or reposition relative to one another during respective expansion and contraction of the stented graft, the manufacturing methods and materials of the present invention render the PTFE sufficiently strong and sufficiently firmly laminated or fused so as to permit such relative movement of the individual members of the stent without tearing or rupturing of the tubular PTFE graft.

Further objects and advantages of the invention will become apparent to those skilled in the art upon reading and understanding the following detailed description and the accompanying drawings.

Brief Description of the Drawings

Figure 1 is a perspective view of an integrally stented PTFE tubular graft of the present invention, wherein a portion of the graft has been inserted into a tubular catheter.

Figure 1a is an enlarged perspective view of a segment of Figure 1.

Figure 2 is an enlarged, cut-away, elevational view of a preferred, integrally stented, tubular PTFE graft of the present invention.

Figure 3a is an enlarged perspective view of a portion of the stent incorporated in the graft of Figure 2.

Figure 3b is an enlarged cross-sectional view through line 3b-3d of Figure 3a.

Figures 4a-4f are a step-by-step illustration of a preferred method for manufacturing an integrally stented PTFE graft of the present invention.

Figure 5 is a schematic illustration of an alternative electron beam deposition method which is usable for depositing PTFE coating on the stent portion of the integrally stented PTFE grafts of the present invention.

Figure 6 is a perspective view of an alternative heating apparatus which is useable in the manufacture of the integrally stented PTFE grafts of the present invention.

Detailed Description of the Preferred Embodiments

The following detailed description is provided for the purpose of describing and illustrating presently preferred embodiments of the invention only, and is not intended to exhaustively describe all possible embodiments in which the invention may be practiced.

A. The Structure of an Integrally Stented PTFE Graft

With reference to Figures 1-3b, there is shown an integrally stented tubular PTFE graft 10 of the present invention. The preferred integrally stented graft 10 comprises a tubular PTFE base graft 12, a PTFE-coated stent 14 and an outer layer of PTFE 16.

One of the many types of stents which may be used to form the stent 14 component of a stented graft 10 of the present invention, is shown in the drawings. This particular stent 14 is formed of individual elements or wires 18 which have been coated with a PTFE coating 20. Gaps or lateral openings 19 exist between adjacent ones or bundles of the wires 18. The configuration, construction, and function of this stent 14 is described

in detail in United States Patent Nos. 4,655,771 Wallsten); 4,954,126 (Wallsten); and 5,061,275 (Wallsten et al.), the entireties of which are hereby expressly incorporated herein by reference. As shown in the figures of this patent application, this particular stent 14 is composed of rigid but resiliently flexible thread elements or wires 18. These thread elements or wires 18 are formed of metal, such as an alloy of cobalt, chromium, nickel or molybdenum, wherein the alloying residue is iron. One specific example of a commercially available alloy which may is usable to form the wires 18 of the stent 14 is Elgiloy (The Elgiloy Company, 1565 Fleetwood Drive, Elgin, IL 60120). The wires 18 of this stent 14 are arranged in helical configuration about a common longitudinal axis LA. A number of the wires 18 are positioned in substantially parallel relation to one another, but are axially displaced relative to each other. By such arrangement, some of the wires 18 are wound in a first helical direction, while others are wound in a second or opposite helical direction such that they cross on opposite sides of adjacent ones of the wires wound in the first helical direction so as to form a helically braided wire stent as shown in the Figures. This results in the formation of a braided wire stent 14 of generally tubular configuration which is self-expanding and biased to it's radially expanded diameter D_2. However, this stent 14 may be radially compressed to a smaller diameter D_1 and radial constraint, as may be applied by the surrounding wall of the tubular delivery catheter 22 shown in Figure 1, may be applied to hold the stent 14 in such radially compressed state (diameter D_1). Thereafter, when the radial constraint is removed from the stent 14, the stent 14 will resiliently spring back to its radially expanded diameter D_2. The individual, helically wound wires 18 of this particular braided stent 14 move and articulate such that the angular dispositions of the wires 18, relative to one another, will change

radial expansion and compression of the stent 14. Also, the longitudinal length of the stent 14 will increase as the stent 14 is radially compressed toward its radially compact configuration D_1, and such length will shorten as the stent 14 expands toward its radially expanded configuration D_2. Thus, is the optional PTFE coating 20 is applied to the wires 18 of the stent 14, such coating (described in detail herebelow) is preferably flexible enough to withstand the flexing and movement of the individual wires 18 without cracking or degrading.

The tubular base graft 12 is initially coaxially positioned within the hollow inner bore of the tubular stent 14 while the stent 14 is in it's radially expanded configuration, after the stent 14 has been coated with the PTFE coating 20, if desired. Thereafter, the outer PTFE layer 16 is formed by any suitable means, such as by wrapping PTFE tape 17 upon the outer surface of the PTFE coated stent 14 to form the generally tubular outer PTFE layer 16. Thereafter, heat or other means are utilized to fuse the outer PTFE layer 16 to the inner base graft 12, through the gaps or openings 19 which exist in the stent 14. In embodiments wherein the optional PTFE coating 20 has been applied to the stent 14, such heating will also facilitate bonding of the PTFE coating 20 of the stent 14 to the adjacent base graft 12 and outer PTFE layer 16. In this manner, there is formed a self-expanding, tubular, integrally stented, PTFE graft 10 of substantially unitary construction. The stent 14 forms an integral structural framework within the tubular graft 10, and the fused PTFE body of the graft is low enough in density and sufficiently pliable to allow the stent 14 incorporated into the graft 10 to continue to undergo substantially the same range of radial expansion and contraction that such stent 14 was capable of before disposition of the PTFE graft thereon. In this regard, the internally stented graft 10 is radially compressible to the stent's first diameter D_1 and may be may be

inserted into the lumen of a small diameter tubular catheter 22. The external constraint provided by the wall of the catheter 22 will maintain the stented graft 10 in it's radially compressed configuration of diameter D_1 until such time as the graft 10 is expelled or ejected out of the catheter 22. After the graft 10 has been expelled or ejected out of the catheter 22, the graft will self-expand to a diameter which is substantially equal to the original expanded diameter D_2 of the stent 14.

B. **Preparation of the Tubular Base Graft**

i.) Preparation of Paste

The manufacture of the tubular base graft begins with the step of preparing a PTFE paste dispersion for subsequent extrusion. This PTFE paste dispersion may be prepared by known methodology whereby a fine, virgin PTFE powder (e.g., F-104 or F-103 Virgin PTFE Fine Powder, Dakin America, 20 Olympic Drive, Orangebury, NY 10962) is blended with a liquid lubricant, such as odorless mineral spirits (e.g., Isopar®, Exxon Chemical Company, Houston, TX 77253-3272), to form a PTFE paste of the desired consistency.

ii.) Extrusion of Tube

The PTFE-lubricant blend dispersion is subsequently passed through a tubular extrusion dye to form a tubular extrudate.

iii.) Drying

The wet tubular extrudate is then subjected to a drying step whereby the liquid lubricant is removed. This drying step may be accomplished at room temperature or by placing the wet tubular extrudate in an oven maintained at an elevated temperature at or near the lubricant's dry point for a sufficient period of time to result in evaporation of substantially all of the liquid lubricant.

iv.) Expansion

Thereafter, the dried tubular extrudate is longitudinally expanded or longitudinally drawn at a temperature less than 327°c and typically in the range of 250-326°c. This longitudinal expansion of the extrudate may be accomplished through the use of known methodology, and may be implemented by the use of a device known as a batch expander. Typically, the tubular extrudate is longitudinally expanded by an expansion ratio of more than two to one (2:1) (i.e., at least two (2) times its original length).

Preferably, the base graft 12 is formed of expanded, sintered PTFE having a density of less than 1.6 grams per cubic centimeter.

v.) Sintering

After the longitudinal expansion step has been completed, the expanded PTFE tube is subjected to a sintering step whereby it is heated to a temperature above the sintering temperature of PTFE (i.e., 350-370°c) to effect amorphous-locking of the PTFE polymer. The methodology used to effect the sintering step, and the devices used to implement such methodology, are known in the art.

Completion of the sintering step marks the completion of the preparation of the expanded, sintered PTFE base graft 12.

The PTFE tape 16 may be manufactured by any suitable method, including the general method for manufacturing expanded PTFE tape, as follows:

C. Preparation of PTFE Tape

i.) Preparation of Paste Dispersion

The usual manufacture of an expanded, sintered PTFE tape 17 useable to form the outer PTFE layer 16 of the stented graft 10 begins with the preparation of a PTFE paste dispersion. This PTFE paste dispersion may be prepared in the same manner as described hereabove for

preparation of the PTFE paste dispersion used to form the tubular base graft.

ii.) Extrusion of Film

The PTFE paste dispersion is subsequently passed through the film extrusion dye to form a wet film extrudate. The wet film extrudate is taken up or wound upon a rotating core so as to form a roll of the wet film extrudate.

iii.) Calendaring

The wet film extrudate is subsequently unrolled and subjected to an initial cold (i.e., <100°c) calendaring step by passing the film through at least one set of opposing stainless steel calendaring rollers having an adjustable gap thickness therebetween. The calendaring rollers are preferably maintained at a temperature between room temperature and 60°c. The width of the wet extrudate is held constant as it passes through these calendaring rollers. The thickness of the wet film extrudate is reduced to its desired final thickness (e.g., 0.004-0.005 inches) while the width of the film is maintained constant. It will be appreciated that, since the width of the film is maintained constant, the passage of the film through the calendaring machine will result in a longitudinal lengthening of the film. The amount of longitudinal lengthening will be a function of the decrease in film thickness which occurs as the film passes between the calendaring rollers.

One example of a commercially available calendaring machine useable for this purpose is the small Killion 2 Roll Stack, (Killion Extruders, Inc., Cedar Grove, NJ 07009.)

iv) Drying

Thereafter, the wet film is subjected to a drying step. This drying step may be accomplished by permitting or causing the liquid lubricant to evaporate from the matrix of the film. Such evaporation of the liquid lubricant may be facilitated by passing the film over a

drum or roller which is maintained in an elevated temperature sufficient to cause the liquid lubricant to fully evaporate from the film matrix.

v) Expansion

Separately, or concurrently with the drying step the film is subjected to an expansion step. Such expansion step comprises expanding the PTFE film in at least one direction (e.g., longitudinally). Such expansion of the film serves to a) increase the porosity of the film, b) increase the strength of the film, and c) orient the PTFE fibrils in the direction of the axis of expansion.

This expansion step is typically carried out with some heating of the film during such expansion, but such heating does not exceed the crystalline melting point of the PTFE polymer.

vi) Sintering of the Film

After the drying step and expansion step have been completed, the film is subjected to a sintering step wherein the film is heated to a temperature above the melting point of PTFE to accomplish sintering or amorphous locking of the PTFE polymer. This sintering step may be carried out by passing the film over a drum or roller which is maintained at a high surface temperature (e.g., 350-420°c) to cause the desired heating of the PTFE film above the melting point of the PTFE polymer for a sufficient period of time to effect the desired sintering of the film.

vii) Cutting the Film Into Strips

After the film has been dried, the film is cut into strips, each strip typically having a width of 0.25-0.50 inches, thereby creating strips of expanded, sintered PTFE tape 14.

D. Coating of the Stent and/or Deposition of PTFE Between Layers to Enhance Bonding

Prior to assembly of the components of the integrally stented graft 10, the stent 14 may be coated with a polymer coating 20.

The polymer coating formed on the stent 14 may be any suitable type of polymer which will adhere to PTFE. Examples of polymers which may be used for such polymer coating or covering include polytetrafluoroethylene(PTFE), fluorinated ethylene propylene (FEP), polytetrafluoroethylene-perfluoroalkyl vinyl ether copolymer (PFA), polyvinyl chloride (PVC), polypropylene (PP), polyethylene terephthalate (PET) polyuinylidene fluoride (PVDF) and other biocompatable plastics.

One manner in which such coating of the stent 14 may be carried out is illustrated in Figure 4a. As shown in Figure 4a, the stent 14 may be immersed in a vessel 30 containing an aqueous dispersion of PTFE 32. One aqueous PTFE dispersion which may be useable for coating of the stent 14 is DuPont T-30 Aqueous PTFE Dispersion, available commercially from the E.I. DuPont de Numoris Co., (Wilmington, Delaware). Another commercially available PTFE dispersion 32 which may be utilized for coating of the stent is Daikin-Polyflon TFE Dispersion, available from Daikin Industries, Ltd., Chemical Division (Umeda Center Bldg., 4-12 chome, Nakazaki-nishi, Kita-ku, Osaka, Japan).

The time in which the stent 14 must remain immersed in the liquid PTFE dispersion 32 may vary, depending on the construction of the stent 14 and the chemical composition of the PTFE dispersion 32. However, in most cases, an immersion time of 10-15 seconds will be sufficient to obtain uniform deposition of the PTFE coating 20 on the wire members 18 of the stent 14.

After the stent 14 has been removed from the liquid PTFE dispersion 32, it will be permitted to air dry such that a dry PTFE coating 20 remains deposited upon the outer surface of each wire 18 of the stent 14.

Optionally, after the air drying has been completed, the PTFE coated stent 14 may be placed in an oven at 350°c for approximately 10 minutes to sinter the PTFE

coating and/or to enhance the bonding of the PTFE coating 20 to wire members 18 of the stent 14. Sintering of the PTFE coating renders the coating more resistant to abrasion or peeling during the subsequent handing of the stent and/or the ensuing manufacture and use of the stented graft 10. It will be appreciated that various alternative methods, other than immersion, may be used for depositing the PTFE coating 20 on the stent 14. One alternative method is electron beam deposition, as illustrated in Figure 5. In accordance with this alternative PTFE deposition method, the stent 14 is positioned within a closed vacuum chamber 36 wherein a mass of PTFE 38 is located. An electron beam apparatus 40 is then utilized to project electron beam radiation onto the PTFE 38 within the chamber 36 so as to cause sublimation of the PTFE and resultant deposition of the layer 20 of PTFE on the outer surface of the stent 14. The apparatus and specific methodology useable to perform this electron beam deposition of the PTFE coating 20 are well known to those of skill in the relevant art.

As with the above-described immersion process (Fig. 4a), the stent 14 whereupon the PTFE coating 20 has been deposited may be subjected to optional heating at 350°c for a period of approximately ten minutes in order to sinter the PTFE coating and/or to enhance the bonding of the PTFE coating 20 to the wire members 18 of the stent 14.

As an alternative to coating of the stent, or in addition thereto, such PTFE aqueous dispersion may be painted onto the outer surface of the base graft 12, or the inner surface of the outer tubular layer 16, or may be otherwise disposed between the base graft 12 and outer tubular layer 16 to facilitate fusion or bonding of the inner base graft 12 to the outer tubular layer 16. Or, such PTFE aqueous dispersion may be sprayed or otherwise applied to the outer surface of the outer tubular layer 16 provided that the PTFE present in the dispersion are

small enough to migrate inwardly through pores in the outer tubular layer 16, thereby becoming deposited between the outer tubular layer 16 and the inner base graft 12.

Another alternative or additional means by which adherence or fusion of the base graft 12, outer tubular layer 16 and/or stent 14 may be facilitated or enhanced includes the deposition of raw PTFE resin powder between the outer tubular layer 16 and inner base graft 12, and/or upon the stent 14.

It will be appreciated that in many cases, it will be desirable to apply the polymer coating 20 to the stent 14 while the stent 14 is in it's fully radially expanded configuration of diameter D_2. In this manner, after the coating 20 has been applied and formed on the fully radially expanded stent 14, the stent 14 may subsequently be contracted to it's radially compact configuration of diameter D_1 without tearing or disrupting of the previously-applied coating 20. In embodiments which utilize a pressure-expandable stent 14, it may thus be necessary to volitionally or purposely expand the stent 14 to it's fully radially expanded diameter D_2 prior to application of the coating 20. Alternatively, when the stent 14 is of the self-expanding variety it will, in most cases, automatically assume it's fully radially expanded configuration of diameter D_2 and no such volitional or purposeful pre-expansion of the stent 14 will be required.

The preferred means by which liquid PTFE dispersion and/or solid PTFE powder may be deposited between the outer tubular layer 16, and inner base graft 12 will be discussed in more detail herebelow with reference to the manufacturing methodology.

E. <u>Assembly and Construction of the Integrally Stented PTFE Graft</u>

Figures 4b-4f show, in step-wise fashion, the preferred method for assembling and constructing the

integrally stented PTFE graft 10.

As shown in Figure 4b, the tubular base graft 12 is initially disposed on a rod or mandrel 50. Such rod or mandrel 50 may comprise a stainless steel rod having an outer diameter which is only slightly smaller than the inner diameter of the tubular base graft 12. In this manner, the tubular base graft 12 may be slidably advanced onto the outer surface of the mandrel 50 without undue effort or damage to the base graft 12.

Thereafter, the PTFE-coated stent 14 is axially advanced onto the outer surface of the tubular base graft 12, as shown in Figure 4c.

At this point in the process, PTFE liquid dispersion or powdered PTFE resin may be additionally (optionally) applied to the stent 14 and/or outer surface of the base graft 12 to promote further bonding and fusion of the base graft 12 to the stent 14 and/or subsequently applied outer layer 16. In this regard, the mandrel-borne tubular base graft 12 and stent 14 may be rolled in powdered PTFE resin to accomplish the desired deposition of PTFE powder thereon. Alternatively, the above-described PTFE liquid dispersion may be painted sprayed or otherwise applied to the surface of the stent 14 and/or outer surface of the tubular base graft 12 prior to subsequent application of the outer tubular layer 16.

Thereafter, as shown in Figure 4d, the tape 17 is initially helically wrapped in overlapping fashion, on the outer surface of the stent 14, in a first direction. In the preferred embodiment, tape of 1/2 inch width is used. The tape is helically wrapped about the stent at a pitch angle whereby 6 to 8 revolutions of the tape are applied per linear inch of the stent 14.

Thereafter, as shown in Figure 4e, a second tape wrap in the opposite direction is accomplished, preferably using the same width of tape at the same pitch angle, thereby applying another 6-8 revolutions of tape 17 per linear inch of stent 14. In this manner, both

wrappings of the tape 17 (Figs. 4d and 4e) combine to form a tubular, outer PTFE layer 16 which preferably has a thickness of less than 0.1 inches, and which may be formed of 1 to 10 consecutive (e.g., laminated) layers of the tape 17. for example, when using ePTFE tape of less than 1.6g/cc density and ½ inch width, the first helical wrap (Fig. 4d) may deposit four consecutive layers of tape 17 and the second helical wrap (Fig. 4e) may deposit an additional 4 layers of tape 17, thereby resulting in an outer tubular layer 16 which is made up of a total of 8 layers of such tape 17.

Optionally, to further promote bonding of the outer tubular layer 16 to the stent 14 and/or inner base graft 12, liquid PTFE dispersion may be sprayed, painted or otherwise applied to and dried upon the tape 17 prior to wrapping, or such liquid PTFE dispersion may be deposited by any suitable means (spraying, painting, etc.) between the outer tubular layer 16 formed by the helically wrapped tape 17 and the inner base graft 12. Or such liquid PTFE dispersion may be sprayed onto or otherwise applied to the outer surface of the helically wrapped tape 17 such the small particles of PTFE contained within the liquid dispersion will migrate inwardly through pores in the layers of tape 17, and will thereby become deposited between the outer tubular layer 16 and the inner base graft 12 prior to subsequent heating of the assembly, as described herebelow. Another alternative (and optional) method for depositing polymer (e.g., PTFE) particles between the base graft 12 and outer tubular layer 16 is by rolling the mandrel 50, having the base graft 12 and stent 14 disposed thereon, in dry, powdered polymer resin (e.g., the above-described PTFE resin) to cause such dry polymer resin to become deposited on the outer surface of the base graft 12 and/or stent 14 prior to application of the tape 17 as shown in Figures 4d and 4e.

Thereafter, as shown in Figure 4f, ligatures 52 of stainless steel wire are tied about the opposite ends of the graft 10 so as to securely hold the base graft 12, PTFE-coated stent 14 and outer layer 16 on the mandrel 50. The mandrel, having the graft 10 disposed thereon is then heated to a temperature of 363° ± 2°c for thirty minutes. Such heating will cause the outer PTFE layer 16 to heat fuse to the inner base graft 12 through the openings 19 which exist in the stent 14, and will further facilitate bonding or fusing of the PTFE coating 20 of the stent 14 to the adjacent base graft 12 and outer tape layer 16. In this manner, the desired integrally-stented PTFE tubular graft 10 is formed.

The heating step illustrated schematically in Figure 4f may be carried out by any suitable means. For example, the mandrel 50 having the graft 10 and ligatures 52 disposed thereon may be placed in an oven preheated to the desired temperature, for the desired period of time. Alternatively, the mandrel, having the graft 10 and ligatures 52 disposed thereon may be rolled on a hot plate or heated surface to accomplish the desired heat fusing or bonding of the outer layer 16, base graft 12 and PTFE coating 20 of the stent 14.

Another alternative apparatus which may be utilized for the heating step shown schematically in Figure 4f, is the U-shaped aluminum block heater shown in Figure 6. This aluminum block heater is formed of a solid aluminum plate or block 54 formed into a generally U-shaped configuration, and having a plurality of bore holes 60 formed longitudinally therein and extending at least part way therethrough. Elongate, cylindrical, electric heaters 62, such as those commercially available from the Watlow Electric Company, 12001 Lackland Road, St. Louis, MO 63146, are inserted into the bore holes 60, and such heaters 62 are heated to a temperature which will cause the inner surface of the U-shaped aluminum heater block 54 to be maintained at approximately 300°c or greater.

It will be appreciated that other types of heating apparatus, such as electrical strip heaters mounted on the outer surface of the U-shaped block 54, may be useable as an alternative to the bore holes 60 and cylindrical heaters 62 described herein.

After the U-shaped block 54 has been heated to the desired temperature, the mandrel 50, having the graft 10 and ligatures 52 disposed thereon, is inserted into the U-shaped inner region of the block 54, and is rotated, therein so as to accomplish the desired heat fusing of the tubular base graft 12, outer tape layer 16 and PTFE coating 20 of the stent 14.

In many applications, it will be desirable to post-flex and re-expand the stented graft 10 to ensure that the stented graft 10 is capable of undergoing full radial compression and full radial expansion, over it's complete range of intended diameters.

To accomplish this post-flexing and re-expansion of the stented graft 10, the stented graft 10 is removed from the mandrel 50 and is held in a heated environment, such as in the inner space of the U-shaped heater device shown in Figure 6. Thereafter, the opposite ends of the stent 14 are pulled longitudinally away from each other to thereby radially contract the stented graft 10 to it's minimal radially compressed diameter D_1. Thereafter, the stented graft 10 is allowed to self-expand. If this self-expansion of the stented graft 10 does not result in return of the stented graft 10 to its fully radially expanded diameter D_2, the stented graft 10 may then be re-advanced onto the mandrel 50 to thereby force the stented graft 10 to reassume it's full radially expanded configuration of diameter D_2.

Thereafter, when the graft is again removed from the mandrel 50, the stented graft 10 will be rendered capable of being radially compressed to it's fully compressed diameter D_1, and subsequently self-expanded to it's full radially expanded diameter D_2.

F. **Assembly and Construction of Internally Stented PTFE Tube Graft**

In a first alternative embodiment of the invention, the inner base graft 12 may be eliminated or excluded, thereby providing a modified version of the stented graft 10 comprising only the stent 14 and outer tubular layer 16.

In this first alternative embodiment, the above-described manufacturing method is performed as described without the tubular base graft 12, thereby forming a modified version of the stented graft 10 wherein the outer tubular layer 16 of PTFE is fused only to the stent 14.

In embodiments wherein the stent 14 is coated with a polymer coating such as PTFE, the presence of such coating on the stent 14 will provide lubricity and biocompatability, which may render such internally stented graft suitable for use in applications wherein the exposed stent 14 will come in direct contact with biological fluid or blood flowing through the graft, thereby avoiding the need for use of the internal base graft 12.

Thus, this first alternative embodiment of the present invention includes all possible embodiments wherein only the outer tubular layer 16 is utilized in conjunction with the stent 14, to provide an internally stented graft 10 which is devoid of any internal tubular base graft 12.

G. **Assembly and Construction of Externally Stented PTFE Tube Graft**

In a second alternative embodiment of the invention, the outer tubular layer 16 may be excluded or eliminated, thereby providing an externally stented PTFE tube graft which comprises only the stent 14 and the inner-base tube 12.

In this second alternative embodiment, the above-described manufacturing method is performed as described

without the outer tubular layer 16. This results in the formation of a modified version of the stented graft 10, comprising only the inner base graft 12 and the stent 14.

In embodiments wherein the stent 14 is coated with a polymer coating, such as PTFE, the presence of such coating on the stent 14 will provide for enhanced biocompatability, which may render such externally stented graft suitable for implantation in blood vessels or other tubular anatomical passageways wherein the exposed exterior of the coated stent 14 comes in direct contact with vascular tissue or other tissue of the body, thereby avoiding the need for use of the outer tubular layer 16.

Thus, this second alternative embodiment of the present invention includes all possible embodiments wherein only the inner base graft 12 is utilized in conjunction with the stent 14, to provide an externally stented graft 10 which is devoid of any outer tubular layer 16.

It will be appreciated that the invention has been described hereabove with reference to certain presently preferred embodiments of the invention. Various additions, deletions, alterations and modifications may be made to the above-described embodiments without departing from the intended spirit and scope of the invention. Accordingly, it is intended that all such reasonable additions, deletions, modifications and alterations to the above described embodiments be included within the scope of the following claims.

WHAT IS CLAIMED IS:

1. A tubular stented graft which is alternately deployable in a radially compact configuration having a first diameter and a radially expanded configuration having a second diameter, said stented graft comprising:

a) a stent comprising:

i) at least one member formed in a generally cylindrical shape having a hollow bore which extends longitudinally therethrough;

ii) said stent being initially radially collapsible to a diameter which is substantially equal to said first diameter of the stented graft, and subsequently radially expandable to a diameter which is substantially equal to said second diameter of the stented graft; and,

iii) a plurality of lateral openings existing in said stent when said stent is at it's radially expanded second diameter;

b) a continuous, tubular PTFE covering formed on said stent, said PTFE covering comprising:

i. a tubular base graft formed of expanded, sintered PTFE, said tubular base graft having an outer surface and an inner surface, said tubular base graft being deployed coaxially within the lumen of said stent such that the outer surface of the tubular base graft is in contact with the inner surface of the stent, and the inner surface of said tubular base graft thereby defining a luminal passageway through the stented graft; and,

ii. a tubular outer layer formed of expanded, sintered PTFE said outer layer being disposed about the outer surface of said stent such that said stent is captured between said

outer layer and said tubular base graft;

said tubular outer layer being attached to said tubular base graft, through said lateral openings in said stent, to thereby form an integrally stented, continuous PTFE tube which is alternately disposable in said radially compact configuration of said first diameter and said radially expanded configuration of said second diameter.

2. The stented graft of Claim 1 wherein said tubular outer layer is formed of expanded, sintered PTFE tape which has a width of less than about 1 inch, said tape having been wound about the stent to create said tubular outer layer thereon.

3. The stented graft of Claim 2 wherein said PTFE tape has a thickness of less than 0.015 inch and wherein said tape has been wound about said stent in overlapping fashion, such that said tubular outer layer comprises 1 to 10 layers of said tape.

4. The stented graft of Claim 2 wherein said tape is helically wrapped about said stent.

5. The stented graft of Claim 4 wherein said tape has a width of 1/2 inch, and wherein said tape is helically wrapped such that 6-8 revolutions of tape are applied per longitudinal inch of the stented graft.

6. The stented graft of Claim 5 wherein said helical wrapping of said tape is applied twice, first in one direction and then in the opposite direction.

7. The stented graft of Claim 6 wherein said helical wrappings of said tape form an outer tubular layer which is made up of 8 consecutive layers of said tape.

8. The stented graft of Claim 1 wherein said stent is a self-expanding stent.

9. The stented graft of Claim 1 wherein said stent is a pressure-expandable stent.

10. The stented graft of Claim 1 wherein said-self-expanding stent is formed of a multiplicity of wire

members which are braided into said generally cylindrical shape, and wherein said lateral openings in the stent are formed by gaps which exist between adjacent wire members.

11. The stented graft of Claim 10 wherein said wire members are formed of a metal alloy wherein the alloying residue is iron and wherein the iron is alloyed with at least one other element selected from the group consisting of:

a) cobalt;

b) chromium;

c) nickel; and,

d) molybdnenium.

12. The stented graft of Claim 1 wherein said stent is formed of a multiplicity of plastic members which are braided into said generally cylindrical shape, and wherein said lateral openings in the stent are formed by gaps which exist between adjacent plastic members.

13. The stented graft of Claim 12 wherein said plastic members are formed of a plastic selected from the group consisting of:

polytetrafluoroethylene;

fluorinated ethylene propylene;

polytetrafluoroethylene-perfluoroalkyl vinyl ether copolymer;

polyvinyl chloride;

polypropylene;

polyethylene terephthalate;

broad fluoride; and,

other biocompatable plastics.

14. The stented graft of Claim 10 wherein some of the wire members of said stent are helically wound about a longitudinal axis in a first direction, and others of said wire members are helically wound about said longitudinal axis in a second direction such that they cross on opposite sides of the wire members which had been wound in the first helical direction, thereby forming a helically braided, cylindrical, wire stent.

15. The stented graft of Claim 8 wherein said-self-expanding stent comprises a shape memory alloy which alternately exists in first and second crystalline states, and wherein the stent will assume it's radially expanded configuration when said shape memory alloy is in it's first crystalline state, and will assume it's radially compact configuration when said shape memory alloy is in it's second crystalline state.

16. The stented graft of Claim 1 wherein said tubular base graft comprises expanded, sintered PTFE of less than 0.10 inch thickness.

17. The stented graft of Claim 1 wherein said tubular base graft comprises expanded, sintered PTFE having a density of less than 1.6 g/cc.

18. The stented graft of Claim 1 wherein tubular base graft comprises expanded, sintered PTFE having a thickness of less than 0.10 inches and a density of less than 1.6 g/cc.

19. The stented graft of Claim 1 wherein said tubular outer layer comprises expanded, sintered PTFE having a thickness of less than 0.1 inch.

20. The stented graft of Claim 1 wherein said tubular outer layer comprises expanded, sintered PTFE having a density of less than 1.6 g/cc.

21. The stented graft of Claim 1 wherein said tubular outer layer comprises expanded, sintered PTFE having a thickness of less than 0.1 inch and a density of less than 1.6 g/cc.

22. The stented graft of Claim 19 wherein said tubular outer layer having a thickness of less than 0.1 inch is formed of expanded, sintered PTFE tape which has a thickness of less than 0.015 inches, said tape being wrapped about said stent in overlapping fashion so as to form said tubular outer layer.

23. The stented graft of Claim 1 wherein said stent further comprises:

iv) a polymer coating formed on said stent.

24. The stented graft of Claim 23 wherein the polymer coating formed on said stent is of a polymer material selected from the group consisting of:

polytetrafluoroethylene;

fluorinated ethylene propylene;

polytetrafluoroethylene-perfluoroalkyl vinyl ether copolymer;

polyvinyl chloride;

polypropylene;

polyethylene terephthalate;

polyvinylidene fluoride; and,

other biocompatable plastics.

25. The stented graft of Claim 23 wherein said polymer coating was applied to said stent by the steps of:

immersing the stent in a liquid polymer dispersion;

removing the stent from the liquid polymer dispersion;

drying that liquid polymer dispersion which has remained on the stent, thereby forming said polymer coating thereon.

26. The stented graft of Claim 23 wherein said polymer coating was formed on the stent by electron beam deposition.

27. The stented graft of Claim 23 wherein said stent is formed of a plurality of elongate members, and wherein said polymer coating was formed on said elongate members by positioning a polymer tube around each elongate member.

28. The stented graft of Claim 23 wherein said base graft and said tubular outer layer are adherent to the polymer coating which is formed on said stent.

29. The stented graft of Claim 1 wherein said graft further comprises:

iv) polymer particles deposited between said inner base graft and said outer tubular layer and subsequently melted to promote attachment of said tubular base graft to said tubular outer layer.

30. The stented graft of Claim 29 wherein said polymer particles are PTFE.

31. The stented graft of Claim 29 wherein said polymer particles are melted by heat.

32. The stented graft of Claim 30 wherein said polymer particles are melted by solvent.

33. The stented graft of Claim 29 wherein said polymer particles are deposited by applying a liquid polymer particle dispersion to one of said base graft and said tubular outer layer, prior to assembly thereof.

34. The stented graft of Claim 29 wherein said polymer particles are deposited between said tubular base graft and said tubular outer layer by applying a liquid dispersion of polymer particles to the exterior of said tubular outer layer, such that the polymer particles contained within the dispersion will migrate inwardly through the tubular outer layer.

35. An externally stented tubular graft which is alternately deployable in a radially compact configuration having a first diameter, and a radially expanded configuration having a second diameter, said externally stented graft comprising:

a) a stent comprising:

i) at least one member formed in a generally cylindrical shape having a hollow bore which extends longitudinally therethrough;

ii) said stent being radially collapsible to a diameter which is substantially equal to said first diameter of the stented graft and radially expandable to a diameter which is substantially equal to said second diameter of the stented graft; and,

iii) a plurality of lateral openings being present in said stent when said stent is at it's radially expanded diameter.

b) a continuous tubular PTFE covering formed on said stent, said PTFE covering comprising a tubular base graft formed of expanded, sintered PTFE, said tubular base graft having an outer surface and an inner surface, said tubular base graft being positioned coaxially within the lumen of said stent such that the outer surface of the tubular base graft is in contact with the stent, the inner surface of said tubular base graft thereby defining a luminal passageway through the bore of the stent;

said tubular base graft being attached to said stent, to thereby form an externally stented, continuous PTFE tube which is alternately disposable in said radially compact configuration of said first diameter and said radially expanded configuration of said second diameter.

36. The externally stented graft of Claim 35 wherein said stent is a self-expanding stent.

37. The externally stented graft of Claim 35 wherein said stent is a pressure-expandable stent.

38. The externally stented graft of Claim 36 wherein said self-expanding stent is formed of a multiplicity of wire members which are braided into said generally cylindrical shape, and wherein said lateral openings in the stent are gaps which exist between adjacent wire members.

39. The externally stented graft of Claim 38 wherein said wire members are formed of an alloy wherein the alloying residue is iron and wherein the iron is alloyed with at least one element selected from the croup consisting of:

a) cobalt;

b) chromium;

c) nickel; and,

d) molybdnenium.

40. The stented graft of Claim 35 wherein said stent is formed of a multiplicity of plastic members which are braided into said generally cylindrical shape, and wherein said lateral openings in the stent are formed by gaps which exist between adjacent plastic members.

41. The stented graft of Claim 40 wherein said plastic members are formed of a plastic selected from the group consisting of:

polytetrafluoroethylene;

fluorinated ethylene propylene;

polytetrafluoroethylene-perfluoroalkyl vinyl ether copolymer;

polyvinyl chloride;

polypropylene;

polyethylene terephthalate;

polyvinylidene fluoride; and,

other biocompatable plastics.

42. The externally stented graft of Claim 38 wherein some of the wire members of said stent are wound in a helix of a first direction, and others of said wire members are wound in a helix of a second direction such that they cross on opposite sides of adjacent ones of the wires wound in the first helical direction, thereby forming a helically braided wire stent.

43. The externally stented graft of Claim 36 wherein said self-expanding stent comprises a shape memory alloy which alternately exists in a first crystalline state and a second crystalline state, such that said stent will assume it's radially compact configuration substantially of said first diameter when said shape memory alloy is in it's first crystalline state and it's radially expanded configuration substantially of said second diameter when said shape memory alloy is in it's second crystalline state.

44. The externally stented graft of Claim 35 wherein said tubular base graft comprises expanded, sintered PTFE of less than 0.10 inch thickness.

45. The externally stented graft of Claim 35 wherein said tubular base graft comprises expanded, sintered PTFE having a density of less than 1.6 g/cc.

46. The externally stented graft of Claim 35 wherein tubular base graft comprises expanded, sintered PTFE having a thickness of less than 0.10 inches and a density of less than 1.6 g/cc.

47. The externally stented graft of Claim 35 wherein said stent further comprises:

iv) a polymer coating formed on said stent.

48. The externally stented graft of Claim 35 wherein the polymer coating formed on said stent is of a polymer material selected from the group consisting of:

polytetrafluoroethylene;

fluorinated ethylene propylene;

polytetrafluoroethylene-perfluoroalkyl vinyl ether copolymer;

polyvinyl chloride;

polypropylene;

polyethylene terephthalate;

polyvinylidene fluoride; and,

other biocompatable plastics.

49. The externally stented graft of Claim 47 wherein said polymer coating is a polymer coating which was applied to said stent by the steps of:

immersing the stent in a liquid polymer dispersion;

removing the stent from the liquid polymer disposition;

drying that liquid polymer dispersion which remains on the stent coating thereon.

50. The externally stented graft of Claim 47 wherein said polymer coating was formed on the stent by

a method of electron beam deposition.

51. The externally stented graft of Claim 47 wherein said stent is formed of a plurality of elongate members and wherein said polymer coating was formed by mounting a previously formed polymer tube about each of said elongate members.

52. The externally stented graft of Claim 47 wherein said base graft and said tubular outer layer are additionally fused to the polymer coating which is formed on said stent.

53. An internally stented tubular graft which is initially deployable in a radially compact configuration having a first outer diameter, and subsequently expandable to a radially expanded configuration having a second outer diameter, said stented graft comprising:

a) a stent comprising:

i) at least one member formed in a generally cylindrical shape having a hollow bore which extends longitudinally therethrough;

ii) said stent being initially radially collapsible to a diameter which is substantially equal to said first diameter of the stented graft, and subsequently radially expandable to a diameter which is substantially equal to said second diameter of the stented graft; and,

iii) a plurality of lateral openings being present in said stent when said stent is at it's radially expanded diameter;

b) a continuous tubular PTFE outer covering formed on said stent, said PTFE outer covering comprising a tubular outer layer of expanded, sintered PTFE, coaxially disposed about the cylindrical stent;

said tubular outer layer being affixed to the stent, to thereby form a continuous, internally

stented PTFE tube which is alternately disposable in said radially compact configuration of said first diameter and said radially expanded configuration of said second diameter.

54. The internally stented graft of Claim 53 wherein said stent is a self-expanding stent.

55. The internally stented graft of Claim 53 wherein said stent is a pressure-expandable stent.

56. The internally stented graft of Claim 54 wherein said self-expanding stent is formed of a multiplicity of wire members which are braided into said generally cylindrical shape, and wherein said lateral openings in the stent are gaps which exist between adjacent ones of said wire members.

57. The internally stented graft of Claim 52 wherein said wire members are formed of a metal alloy wherein the alloying residue is iron, and wherein the iron is alloyed with at least one other element selected from the group consisting of:

a) cobalt;
b) chromium;
c) nickel; and,
d) molybdnenium.

58. The stented graft of Claim 53 wherein said stent is formed of a multiplicity of plastic members which are braided into said generally cylindrical shape, and wherein said lateral openings in the stent are formed by gaps which exist between adjacent plastic members.

59. The stented graft of Claim 58 wherein said plastic members are formed of a plastic selected from the group consisting of:

polytetrafluoroethylene;
fluorinated ethylene propylene;
polytetrafluoroethylene-perfluoroalkyl vinyl ether copolymer;
polyvinyl chloride;
polypropylene;

polyethylene terephthalate;
polyvinylidene fluoride; and,
other biocompatable plastics.

60. The internally stented graft of Claim 56 wherein some of the wire members of said stent are helically wound about a longitudinal axis in a first direction, and others of said wire members are helically wound about said longitudinal axis in a second direction such that they cross on opposite sides of the wire members which had been wound in the first helical direction, thereby forming a helically braided, cylindrical wire stent.

61. The internally stented graft of Claim 53 wherein said self-expanding stent comprises a shape memory alloy which alternately exists in first and second crystalline states, and wherein the stent will assume it's radially expanded configuration when said shape memory alloy is in it's first crystalline state, and will assume it's radially compact configuration when said shape memory alloy is in it's second crystalline state.

62. The internally stented graft of Claim 53 wherein said tubular outer layer is formed of expanded, sintered PTFE tape having a width of less than about 1 inch, said tape having been wound about the outer surface of the stent to create said tubular outer layer.

63. The internally stented graft of Claim 62 wherein said PTFE tape has a thickness of less than 0.015 inch and wherein said tape has been wound about said stent in over lapping fashion such that said outer layer comprises 1 to 10 layers of said tape.

64. The internally stented graft of Claim 62 wherein said tape is helically wrapped about said stent.

65. The internally stented graft of Claim 64 wherein said tape has a width of 1/2 inch, and wherein said tape is helically wrapped such that 6-8 revolutions of tape are applied per longitudinal inch of the stent.

66. The internally stented graft of Claim 65 wherein said helical wrapping of said tape is applied twice, first in one direction and then in the opposite direction.

67. The stented graft of Claim 66 wherein said helical wrappings of said tape form an outer tubular layer which is made up of 8 consecutive layers of said tape.

68. The internally stented graft of Claim 66 wherein said helical wrapping of said tape is initially applied in a first direction, and subsequently applied in a second direction opposite said first direction.

69. The internally stented graft of Claim 53 wherein said stent further comprises:

iv) a polymer coating formed on said stent.

70. The internally stented graft of Claim 69 wherein the polymer coating formed on said stent is of a polymer material selected from the group consisting of:

polytetrafluoroethylene;

fluorinated ethylene propylene;

polytetrafluoroethylene-perfluoroalkyl vinyl ether copolymer;

polyvinyl chloride;

polypropylene;

polyethylene terephthalate;

polyvinylidene fluoride; and,

other biocompatable plastics.

71. The internally stented graft of Claim 69 wherein said polymer coating has been applied to the said stent by the steps of:

immersing the stent in a liquid polymer dispersion;

removing the stent from the liquid polymer disposition;

drying that liquid polymer dispersion which remains on the stent coating thereon.

72. The internally stented graft of Claim 69 wherein said polymer coating was formed on the stent by electron beam deposition.

73. The internally stented graft of Claim 69 wherein said stent comprises a plurality of elongate wire members and wherein said polymer coating was formed on said stent by mounting a previously formed polymer tube about said wire members.

74. The internally stented graft of Claim 69 wherein said outer layer is fused to the polymer coating which is formed on said stent.

75. A method of manufacturing an integrally stented, tubular, PTFE graft which is alternately deployable in a radially compact configuration having a first diameter and a radially expanded configuration having a second diameter, said method comprising the steps of:

a) providing a tubular base graft which comprises expanded, sintered PTFE having a density of less than 1.6 g/cc;

b) positioning the tubular base graft on a cylindrical mandrel;

c) providing a generally cylindrical stent which is alternately radially compressible to a first diameter and radially expandable to a second diameter, said stent having a longitudinal bore extending therethrough and a plurality of lateral openings therein when radially expanded to its second diameter;

d) mounting the generally cylindrical stent over the tubular base graft positioned upon the mandrel, such that the tubular base graft is coaxially disposed within the longitudinal bore of the stent, and is in abutting contact therewith;

e) forming a tubular outer PTFE layer about said stent such that said stent is coaxially

positioned within said tubular outer layer, and is in abutting contact therewith; and,

f) heating the base graft, stent and tubular outer layer while mounted upon said mandrel, to cause the tubular outer layer and tubular base graft to become attached to one another through the lateral openings which exist in the stent, thereby forming said stented, tubular PTFE graft.

76. The method of Claim 75 further comprising the additional steps of:

g) removing the stented, tubular PTFE graft from the mandrel;

h) radially contracting the stented tubular PTFE graft to it's radially compact configuration of said first diameter; and,

i) subsequently re-expanding the stented tubular PTFE graft to it's radially expanded configuration of said second diameter.

77. The method of Claim 76 wherein step i is carried out by advancing the stented, tubular PTFE graft onto a mandrel which has an outer diameter substantially equal to the inner luminal diameter of the stented tubular PTFE graft when in it's radially expanded configuration having said second diameter.

78. The method of Claim 75 wherein step c of the method further comprises coating the stent with a plastic coating which will adhere to PTFE when heated , and wherein step f further comprises causing the tubular outer layer and the tubular base graft to become adherent to the plastic coating formed on the stent.

79. The method of Claim 78 wherein said plastic coating on said stent is a PTFE coating.

80. The method of Claim 79 wherein said PTFE coating is formed on said stent by the steps of:

immersing the stent in an aqueous PTFE dispersion;

removing the stent from the aqueous PTFE

dispersion; and,

drying the aqueous PTFE dispersion which remains on the stent to form said PTFE coating thereon.

81. The method of Claim 75 wherein step e of the method is accomplished by:

providing a quantity of expanded, sintered PTFE tape;

wrapping said expanded, sintered PTFE tape around the exterior of the stent to form said outer tubular layer thereon.

82. The method of Claim 81 wherein the step of wrapping said expanded, sintered PTFE tape around the exterior of the stent to form said outer tubular layer thereon comprises:

helically wrapping PTFE tape in overlapping fashion around the exterior of the stent.

83. The method of Claim 82 wherein said PTFE tape has a width of 1/2 inch, and wherein said tape is helically wrapped such that 6-8 revolutions of tape are applied per longitudinal inch of the stented graft.

84. The method of Claim 77 wherein said helical wrapping of said tape is performed twice first in one direction and then in the opposite direction.

85. The method of Claim 82 wherein said helical wrapping of said tape results in the formation of a tubular outer layer which comprises 8 layers of said tape.

86. The method of Claim 78 wherein said helical wrapping of said tape is initially performed in a first direction, and subsequently performed in a second direction, opposite said first direction.

87. The method of Claim 75 further comprising the additional step of:

depositing polymer particles between said tubular base graft and said tubular outer PTFE layer to facilitate attachment of said tubular base graft

to said tubular outer PTFE layer and to said stent.

88. The method of Claim 87 wherein said polymer particles are PTFE.

89. The method of Claim 87 wherein said depositing of said polymer particles is carried out by depositing an aqueous polymer suspension between tubular inner layer and said tubular outer PTFE layer.

90. The method of Claim 87 wherein said polymer particles are deposited by rolling the mandrel having the inner base graft and stent disposed thereon, in powdered polymer resin to accomplish deposition of polymer particles on the stent and outer surface of the tubular base graft.

91. The method of Claim 90 wherein said powdered polymer resin is raw PTFE resin powder.

92. The method of Claim 75 further comprising the step of:

affixing the ends of the tubular outer layer, and tubular base graft to the mandrel to prevent longitudinal shortening during subsequent heating in step f.

93. A method of manufacturing an externally stented, tubular, PTFE graft which is alternately deployable in a radially compact configuration having a first diameter and a radially expanded configuration having a second diameter, said method comprising the steps of:

a) providing a tubular base graft which comprises expanded, sintered PTFE having a density of less than 1.6 g/cc;

b) positioning the tubular base graft on a cylindrical mandrel;

c) providing a generally cylindrical stent which is alternately radially compressible to a first diameter and radially expandable to a second diameter, said stent having a plurality of lateral

openings therein when at it's radially expanded second diameter;

d) positioning the generally cylindrical stent over the tubular base graft, upon the mandrel, such that the tubular base graft is coaxially disposed within the stent, and is in abutting contact therewith; and,

e) heating the mandrel-borne base graft and stent to cause the tubular base graft to become affixed to the stent, thereby forming an internally stented, tubular PTFE graft.

94. The method of Claim 93 further comprising the additional steps of:

f) removing the externally stented, tubular PTFE graft from the mandrel;

g) causing the internally stented tubular PTFE graft to be reduced to it's radially compact configuration of said first diameter; and,

h) subsequently fully re-expanding the stented tubular PTFE graft to said radially expanded configuration of said second diameter.

95. The method of Claim 94 wherein step h is carried out by advancing the externally stented PTFE tube graft onto a mandrel which has an outer diameter substantially equal to the inner luminal diameter of the externally stented PTFE tube graft in it's radially expanded configuration of said second diameter.

96. The method of Claim 93 wherein step c of the method further comprises coating the stent with a polymer coating which will adhere to PTFE when heated , and wherein step f causes the tubular base graft to become adherent to the polymer coating formed on the stent.

97. The method of Claim 96 wherein said polymer coating on said stent is a PTFE coating.

98. The method of Claim 96 wherein said polymer coating is formed on said stent by the steps of:

immersing the stent in an aqueous particle dispersion;

removing the stent from the aqueous particle dispersion; and,

drying the aqueous polymer dispersion which remains on the stent to form said polymer coating thereon.

99. The method of Claim 98 wherein said aqueous polymer particle dispersion is an aqueous dispersion of PTFE particles.

100. The method of Claim 96 wherein said polymer coating is formed on the stent by electron deposition.

101. The method of Claim 93 further comprising the step of:

affixing the ends of said base graft and said stent to said mandrel to prevent longitudinal shortening during the heating of step e.

102. A method of manufacturing an internally stented, tubular, PTFE graft which is alternately deployable in a radially compact configuration having a first diameter and a radially expanded configuration having a second diameter, said method comprising the steps of:

a) providing a generally cylindrical stent which is alternately radially compressible to a first diameter and radially expandable to a second diameter, said stent having a plurality of lateral openings therein when at it's radially expanded second diameter;

b) positioning the generally cylindrical stent on a cylindrical mandrel;

c) forming a tubular outer PTFE layer about said stent such that the tubular outer layer is in abutting contact with the stent; and,

d) heating the mandrel-borne stent and tubular outer layer, to cause the tubular outer

layer to become affixed to the stent thereby forming an internally stented, tubular PTFE graft.

103. The method of Claim 102 further comprising the additional steps of:

e) removing the internally stented, tubular PTFE graft from the mandrel;

f) causing the internally stented tubular PTFE graft to be reduced to it's radially compact configuration of said first diameter; and,

g) subsequently fully re-expanding the internally stented tubular PTFE graft to said radially expanded configuration of said second diameter.

104. The method of Claim 103 wherein step g is carried out by advancing the stented, tubular PTFE graft onto a mandrel which has an outer diameter substantially equal to the inner luminal diameter of the internally stented tubular PTFE graft, when in it's fully radially expanded configuration having said second diameter.

105. The method of Claim 104 wherein step a of the method further comprises coating the stent with a plastic coating which will adhere to PTFE when heated , and wherein step d further comprises causing the tubular outer layer to become adherent to the polymer coating formed on the stent.

106. The method of Claim 105 wherein said polymer coating on said stent is a PTFE coating.

107. The method of Claim 106 wherein said polymer coating is formed on said stent by the steps of:

immersing the stent in an aqueous polymer dispersion;

removing the stent from the aqueous polymer dispersion; and,

drying the aqueous polymer dispersion which remains on the stent to form said polymer coating thereon.

108. The method of Claim 107 wherein said aqueous polymer particle dispersion is an aqueous dispersion of PTFE particles.

109. The method of Claim 106 wherein said polymer coating is formed on the stent by electron deposition.

110. The method of Claim 103 further comprising the step of:

affixing the ends of said base graft and said stent to said mandrel to prevent longitudinal shortening during the heating of step e.

111. The method of Claim 103 wherein step c of the method is accomplished by:

providing a quantity of expanded, sintered PTFE tape;

wrapping said expanded, sintered PTFE tape around the exterior of the stent to form said outer tubular layer thereon.

112. The method of Claim 111 wherein the step of wrapping said expanded, sintered PTFE tape around the exterior of the stent to form said outer tubular layer thereon comprises:

helically wrapping PTFE tape in overlapping fashion around the exterior of the stent.

113. The method of Claim 111 wherein said PTFE tape has a width of 1/2 inch, and wherein said tape is helically wrapped such that 6-8 revolutions of the tape are applied per longitudinal inch of the stent.

114. The method of Claim 112 wherein said helical wrapping of said tape is performed twice first in one direction and then in the opposite direction.

115. The method of Claim 112 wherein said helical wrapping of said tape results in the formation of a tubular outer layer which comprises 8 layers of said tape.

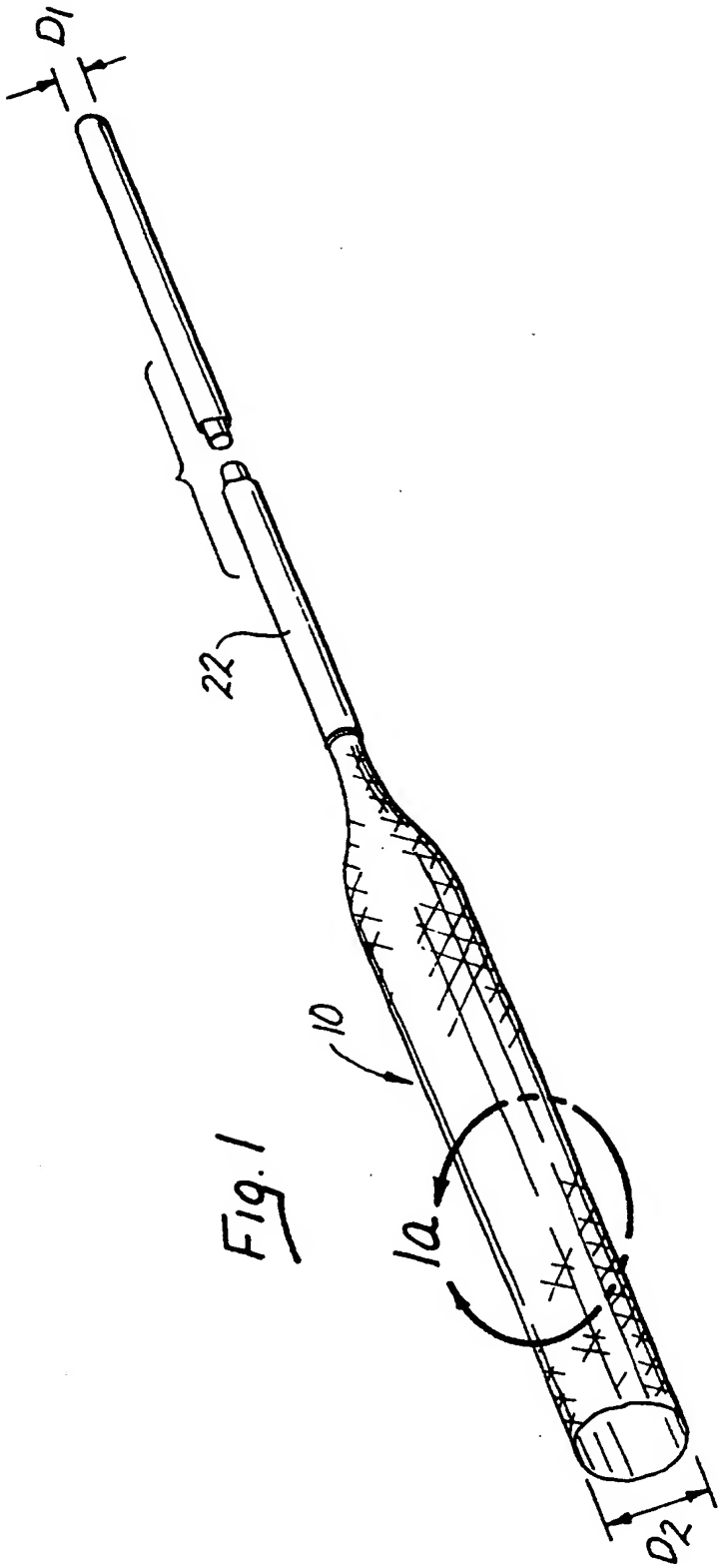


Fig. 1

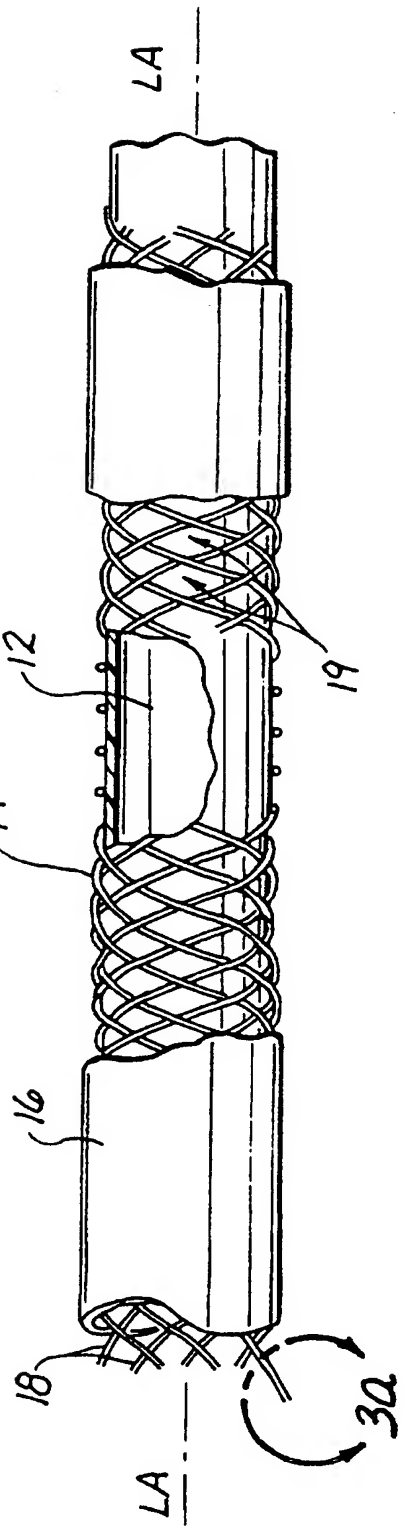


Fig. 2

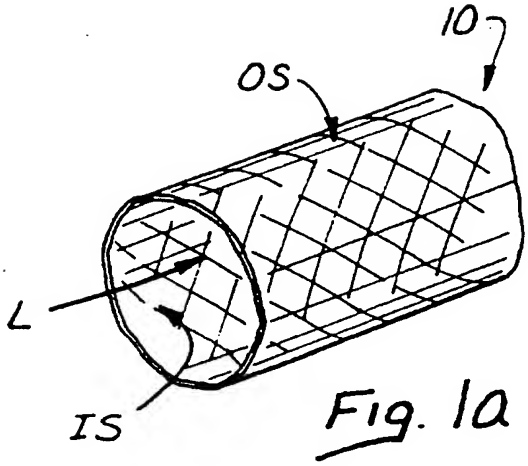


Fig. 1a

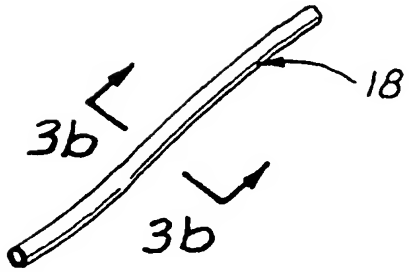


Fig. 3a

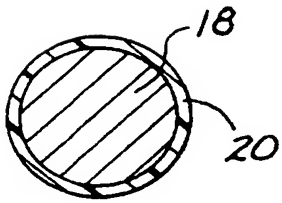


Fig. 3b

Fig. 4a

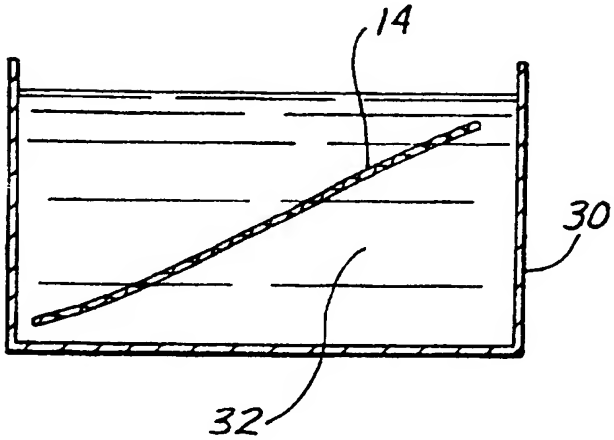
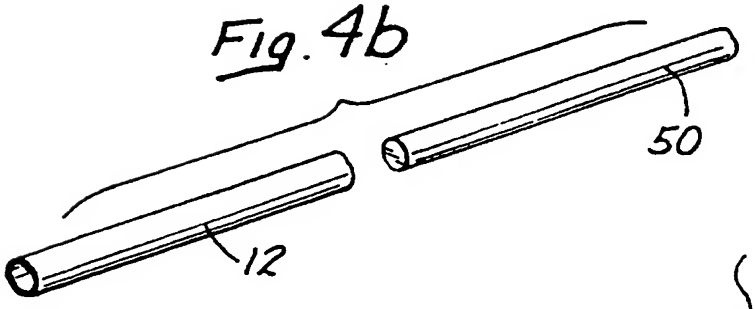


Fig. 4b



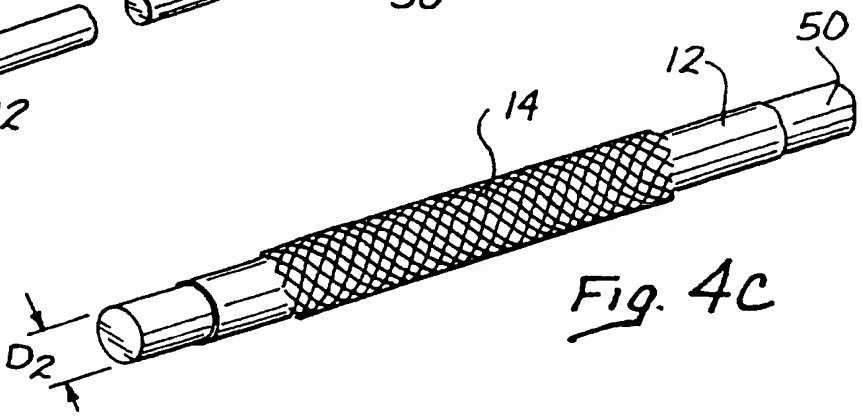


Fig. 4c

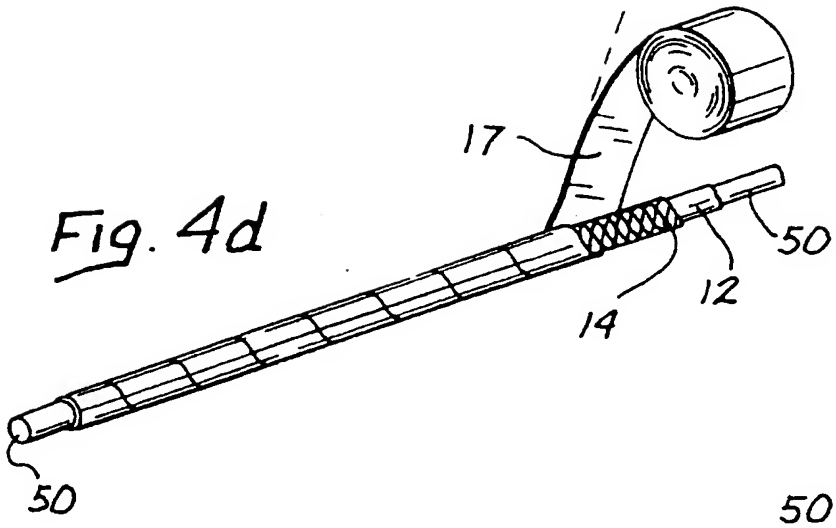


Fig. 4d

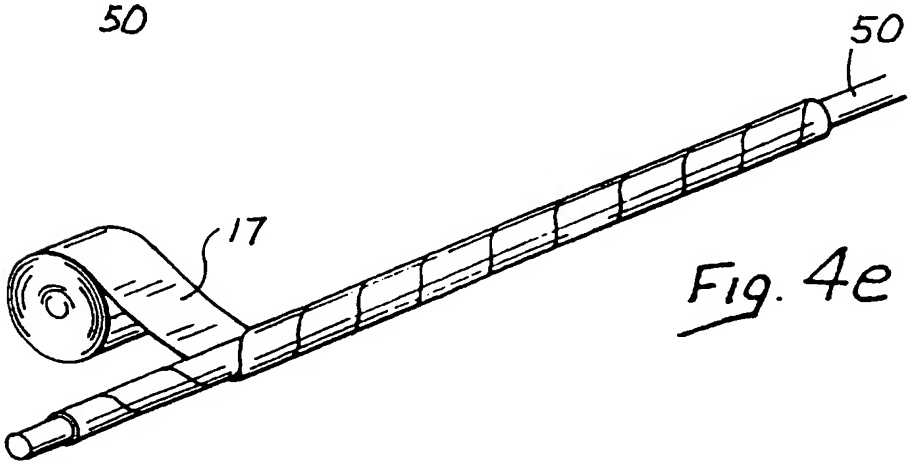


Fig. 4e

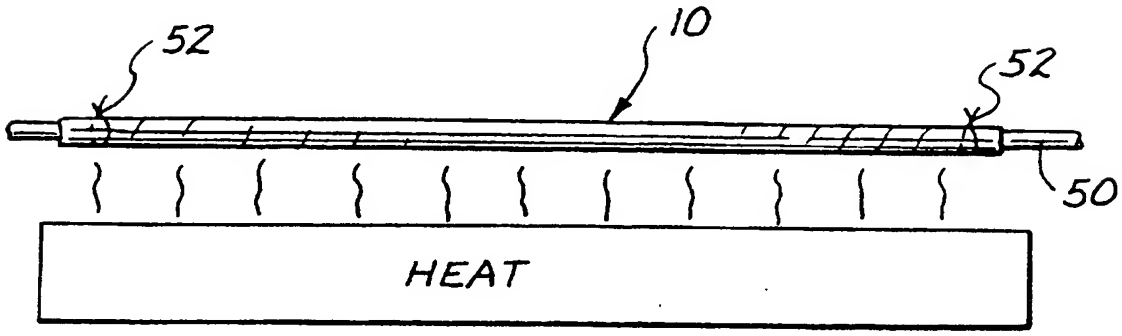


Fig. 4f

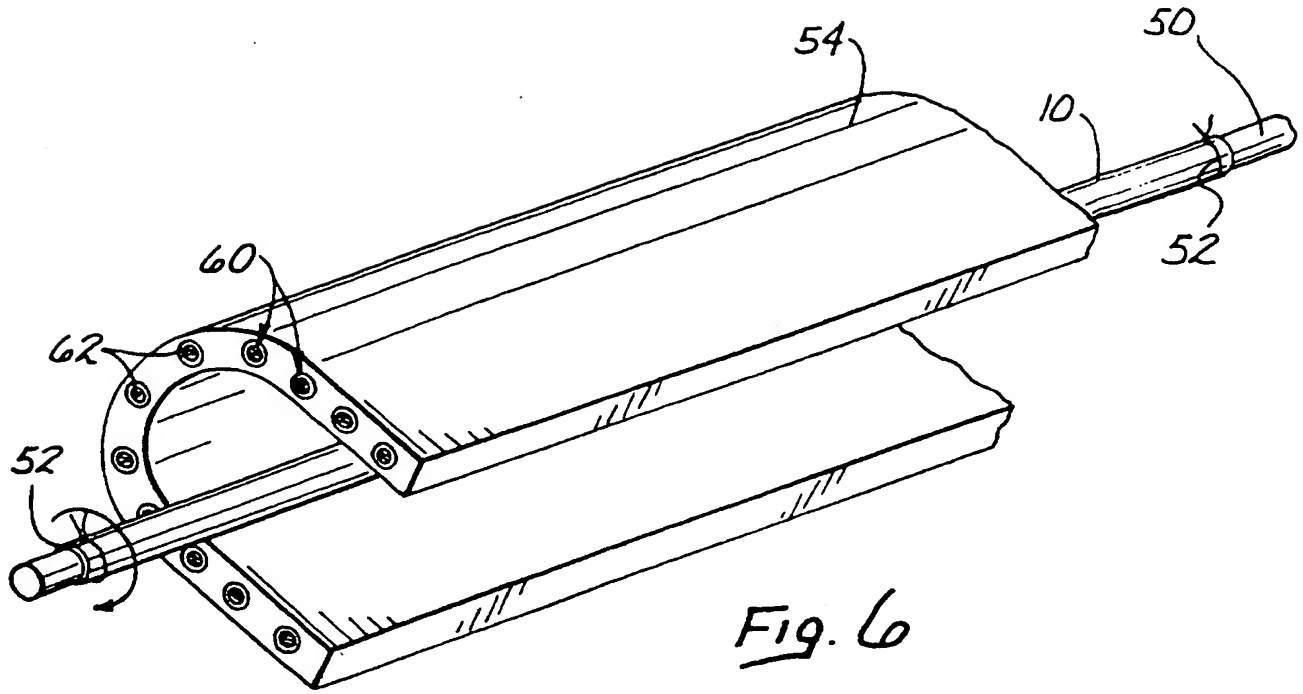


Fig. 6

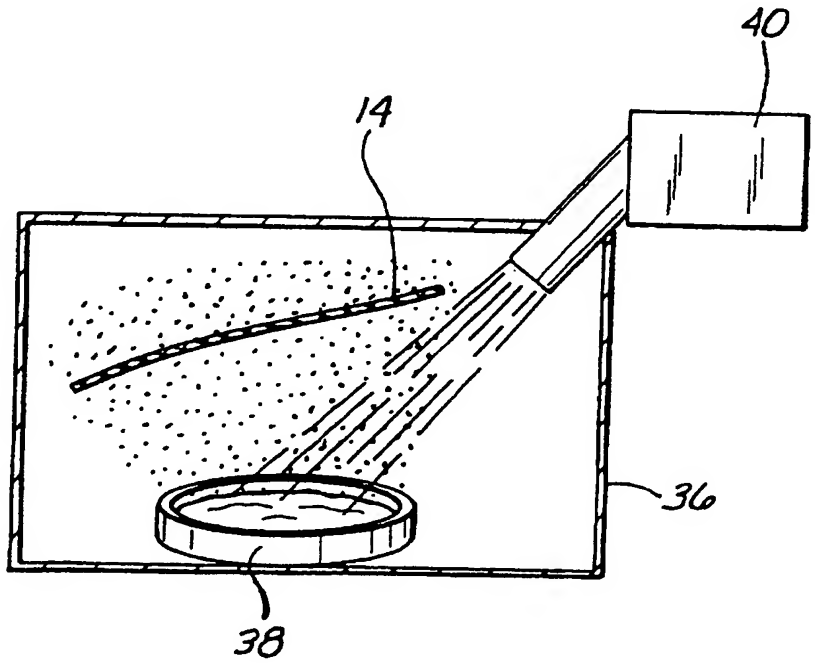


Fig. 5

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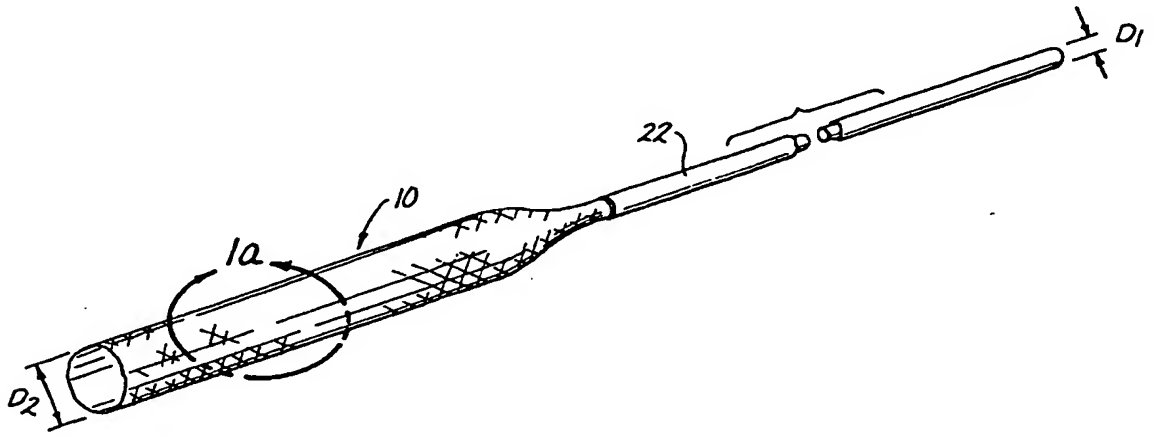
(74) Agents: CANTER, Bruce, M. et al.; Baxter Healthcare Corporation, P.O. Box 15210, Irvine, CA 92623-5210 (US).

(81) Designated States: AL, AM, AT, AU, AZ, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IS, JP, KE, KG, KP, KR, KZ, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, UZ, VN, ARIPO patent (GH, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).

Published
With international search report.

(88) Date of publication of the international search report:
11 June 1998 (11.06.98)

(54) Title: STENTED, RADIALLY EXPANDABLE, TUBULAR PTFE GRAFTS



(57) Abstract

Stented tubular grafts of expanded, sintered polytetrafluoroethylene (PTFE). The stented PTFE grafts of the present invention include an integrally stented embodiment, an externally stented embodiment, and an internally stented embodiment. In each embodiment, the stent may be either self-expanding or pressure-expandable. Also, in each embodiment, the stent may be coated or covered with a plastic material capable of being affixed (e.g., heat fused) to PTFE. Manufacturing methods are also disclosed by the individual components of the stented grafts, are preassembled on a mandrel and are subsequently heated to facilitate attachment of the PTFE layer(s) to one another and/or to the stent. Optionally, the stented graft may be post-flexed and post-expanded following its removal from the mandrel to ensure that the stented graft will be freely radially expandable and/or radially contractible over its full intended range of diameters.

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INTERNATIONAL SEARCH REPORT

Interna al Application No
PCT/US 97/11106

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F2/06 A61L27/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61F A61L

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y A	WO 95 26695 A (PROGRAFT MEDICAL INC.) 12 October 1995 see page 41, line 30 - line 33; figure 26 see page 42, line 20 - line 26; claims	1,35, 75-77,92 2-15, 36-43, 81-86 16,19, 22,44, 54-61,93

X Y A	EP 0 556 850 A (ENDOTECH) 25 August 1993 see the whole document	35,53 54-68 1,93,102

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
27 February 1998	18.03.98

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Steenbakker, J

Form PCT/ISA/210 (second sheet) (July 1992)

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	EP 0 232 543 A (SUMITOMO) 19 August 1987	2-7, 62-68, 81-86
A	see page 2, line 4 - line 11; figures see page 3, line 16 - page 4, line 3 see page 6, line 18 - line 20	111-115

Y	DE 195 24 653 A (WILLY RÜSCH) 27 June 1996	8-11,14, 15, 36-39, 42,43, 54-61
	see the whole document	

Y	GB 2 281 865 A (CORDIS) 22 March 1995	12,13, 40,41
	see page 7, line 26-30 - page 13, paragraph 2; figures	

A	EP 0 177 167 A (THE STERLEY INSTITUTE) 9 April 1986	29, 62-68, 87, 111-115
	see page 2, line 10-47 see page 8, line 14-18	

A	US 5 527 415 A (DOYLE) 18 June 1996	23-28, 47-52, 69-74, 78-80, 96-100, 105-109
	see abstract; claim 3	

A	WO 95 05132 A (GORE) 23 February 1995	16-22, 44-46
	see abstract; figures	

A	US 5 163 951 A (CORVITA CORPORATION) 17 November 1992 see the whole document	29-31, 87-90

A	EP 0 492 481 A (CORVITA CORPORATION) 1 July 1992	

A	DE 39 18 736 A (VALLBRACHT) 13 December 1990	

A	US 4 776 337 A (PALMAZ) 11 October 1988	
	---	
2 A	WO 96 07370 A (GORE) 14 March 1996	
	---	
1 P,X	WO 96 25897 A (MENLO CARE) 29 August 1996 see abstract; figures	1

	-/--	

INTERNATIONAL SEARCH REPORT

Interna al Application No
PCT/US 97/11106

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P,X	WO 96 28115 A (IMPRA) 19 September 1996 see the whole document ---	1
P,X	WO 97 21401 A (IMPRA) 19 June 1997 see page 5, paragraph 3; figures -----	1

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Int. ational application No.
PCT/US 97/ 11106

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

SEE ANNEX

1. ☒ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☒ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International Application No. PCT/ US 97/11106

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

1. Claims: 1, 2-7, 8-15, 75, 76-77, 81-86 , 92

1.1 Claims 1, 2-7, 75, 81-86: A tubular stented graft having an inner and an outer layer attached to each other and its method for manufacturing.
1.2 Claims 1, 8-15: A tubular stented graft having a specific stent.
1.3 Claims 75, 76-77, 92: A specific method for manufacturing a tubular stented graft.

These subjects have been searched.

2. Claims: 1, 16-22

A tubular stented graft having specific dimensioned inner and outer layers.

3. Claims: 1, 23-28, 75, 78-80

A tubular stented graft having a coating on the stent and its method of manufacturing.

4. Claims: 1, 29-34 and 75, 87-91

A tubular stented graft having particles between the inner and outer layer to promote its attachment and its method of manufacturing.

5. Claims: 35, 36-52 and 93, 94-101

An externally stented tubular graft and its method of manufacturing.

6. Claims: 53, 54-74, 102, 103-115

An internally stented tubular graft and its method of manufacturing.

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